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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,015	12/02/2003	Andrew Geall	1530.0610001/EKS/J-H	3181

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/725,015	Applicant(s) GEALL ET AL.	
	Examiner Richard Schnizer, Ph. D	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-27 is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/6/05, 6/4/05, 1/13/06</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-27 are pending and under consideration in this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 02/00844) in view of Hunter et al (US Patent 5,811,088).

As disclosed in the instant specification, Evans taught methods of formulating DNA vaccines by mixing a cationic surfactant such as benzalkonium chloride (BAK), a polyoxypropylene (POP)-polyoxyethylene (POE) copolymer such as CRL 1005, and a polynucleotide at a temperature below the cloud point of the copolymer (about 2-7°C), repeatedly cycling the temperature of the mixture above and below the cloud point of the copolymer. See paragraph bridging pages 32 and 33. The concentration ranges of nucleic acid, copolymer, and cationic surfactant are preferably in the ranges of 0.5-7.5 mg/ml, 1-70 mg/ml, and 0.1-10 mM, respectively (see page 21, line 32 to page 22, line 8).

Evans did not teach that the upper limit of the "above cloud point" temperature range should be 35°C, but MPEP 2144.05 indicates that where the claimed ranges overlap or lie inside ranges disclosed by the prior art a prima facie case of obviousness

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exists, and that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Evans also did not teach cold filtration of the formulation at any step in the process. However, it would have been obvious to one of ordinary skill in the art at the time of the invention that the formulations of Evans, intended for use as vaccines, should be sterile. Hunter taught that solutions comprising poloxamers can be sterilized by passage through a 0.22 micron filter at a cold temperature at which they are soluble. See column 18, lines 40-45. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to cold filter formulations containing poloxamers at a temperature at which they are soluble, i.e. below their cloud point. As to the point in the method of Evans at which filtration would occur, it would clearly save time and materials to sterilize the nucleic acid, copolymer, and cationic surfactant after they had been mixed, rather than separately and individually prior to mixing. So filtration of the mixture is considered obvious to one of ordinary skill in the art at the time of the invention. Also, the mere rearrangement of steps would be *prima facie* obvious unless it can be shown that the rearrangement results in new or unexpected results (see MPEP 2144.04 (IV(C))). Thus the invention as a whole was *prima facie* obvious.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 02/00844), and Hunter et al (US Patent 5,811,088) as applied to claims 1-8 and 11-22 above, and further in view of Emanuele et al (US Patent 6,933,286).

The teachings of Evans and Hunter are set forth above and render obvious methods of formulating nucleic acids with POP-POE copolymers and cationic surfactants, and sterilizing the mixtures by cold filtration. In addition to the use of POE-POP-POE copolymers such as CRL 1005, Evans also taught the use of PLURONIC R copolymers, which have the general organization POP-POE-POP required by instant claim 9. See page 22, line 20 or Evans.

Evans did not teach a POP-POE-POP copolymer wherein POP accounted for up to 20 kDa of the mass of the copolymer, and POE represented between 1 and 50% of the copolymer by weight.

Emanuele taught formulations comprising POP-POE-POP copolymers and nucleic acids for delivery to animals. The POP portion accounted for up to 20 kDa of the mass of the copolymer and the POE portion represented from 1-90% of the copolymer by weight. In one embodiment POP was 2500 Da and POE was 10% of the copolymer mass. See the claims especially claims 1-5 and 8-12.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the copolymer of Emanuele in the method of Evans as modified by Hunter. One would have been motivated to do so because Evans suggested the use of POP-POE-POP copolymers, and Martin taught that when making nucleic acid/POP-POE-POP copolymer complexes for in vivo delivery one should use copolymers wherein POP accounted for up to 20 kDa of the mass of the copolymer and POE represented from 1-90% of the copolymer by weight. Thus the invention as a whole was prima facie obvious.

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Conclusion

Claims 23-27 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635